

Rec'd
9 Oct 09

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October 5th, 2009

U. S. Food and Drug Administration
Karen Gale Sego
Compliance Officer
6751 Steger Dr.
Cincinnati, OH. 45237-3097

CERTIFIED MAIL -
RETURN RECEIPT REQUESTED

Re: Notice of the Instant Pending Quasi-Criminal Proceeding and Lack of Fair notice by the FDA

Dear Ms. Sego:

This case has the nature of a quasi-criminal case and must be treated as same because of the severe possible sanctions. Goldberg v. Kelly, 25 L. Ed. 2d 287; Greene v. McElroy, 360 U.S. 474 at 496-497; Upton v. S.E.C., 75 F. 3d 92; Village of Hoffman Estates v. Flipside, Hoffman Estates, 455 U.S. 489; Joint Anti-Fascist Refugee Committee v. McGrath, 341 U.S. 123; Matthews v. Eldridge, 424 U.S. 319; Addington v. Texas, 441 U.S. 418; United States v. Ward, 448 U.S. 242.

The government alleges that the Respondent has organized and was operating a public business in violation of the FDA through various entities. The Defendant did not know or realize that his conduct was illegal until this alleged complaint was filed against him.

But, due process requires that a person be given fair notice as to what constitutes illegal conduct so that he may conform his conduct to the requirements of the law. United States v. Batchelder, 442 U.S. 114 at 123. Due process requires that penal statutes

define criminal offenses with sufficient clarity that an ordinary person can understand what conduct is prohibited. Kolender v. Lawson, 461 U.S. 352 at 357,

“[A] statute which either forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application violates the first essential of due process of law.” Connally v. General Construction Co., 269 U.S. 385, 391, 46 S.Ct. 126, 127, 70 L.Ed. 322 (1926); accord Papaschristou v. City of Jacksonville, 405 U.S. 156, 161, 163, 92 S.Ct. 839, 843, 31 L.Ed.2d 110 (1972); Lanzetta v. New Jersey, 306 U.S. 451, 453, 59 S.Ct. 618, 619, 83 L.Ed. 888 (1939). Furthermore, “[n]o one may be required at peril of life, liberty or property to speculate as to the meaning of penal statutes. All are entitled to be informed as to what the State commands or forbids.” Lanzetta v. New Jersey, *supra*.

“Due process requires that “laws give the person of ordinary intelligence a reasonable opportunity to know what is prohibited.” Grayned v. City of Rockford, 408 U.S. 104, 108, 92 S.Ct. 2294, 2298-99, 33 L.Ed.2d 222 (1972). Although the FDA’s construction of its own regulations is entitled to “substantial deference,” Lyng v. Payne, 476 U.S. 926, 939, 106 S.Ct. 2333, 2341-42, 90 L.Ed.2d 921 (9186), we cannot defer to the FDA’s interpretation of its rules if doing so would penalize an individual who has not received fair notice of a regulatory violation. See United States v. Matthews, 787 F.2d 38, 49 (2d Cir. 1986). This principle applies, albeit less forcefully, even if the rule in question carries only civil rather than criminal penalties. See Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc., 455 U.S. 489, 498-99, 102 S.Ct. 1186, 1193-94, 71 L.Ed.2d 362 (1982).

Due process requires that a person be given fair notice as to what constitutes illegal conduct so that he may conform his conduct to requirements of the law. U.S. v. Harris, 942 F.2d 1125, Omernick v. Department of Natural Resources, 301 N.W.2d 437; Butz v. Economou, 438 U.S. 478.

The void-for-vagueness doctrine requires that a penal statute define the criminal offense with sufficient definiteness that ordinary people can understand what conduct is prohibited. U.S. v. Walker, 137 F.3d 1217, Winter v. New York, 333 U.S. 507.

There can be no constructive offenses; that before a man can be punished, his case must be plainly and unmistakably within the statute. Chevron, U.S.A., Inc. V. Natural Resources Defense Council, Inc., American Iron and Steel Institute v. Natural Resources Defense Council, Inc., D. Ruckelshaus v. Natural Resources Defense Council, Inc., 467 U.S. 837, 104 S.Ct. 2778.

If there be any fair doubt whether the criminal statute embraces the act, that doubt is to be resolved in favor of the accused. Walter W. Oeflein, Inc. v. State, 188 N.W. 633.

Penal statutes are to be construed narrowly. United States v. Peppas, 13 F.Supp. 669.

The "rule of lenity" is a principle of statutory construction which provides that criminal statutes must be strictly construed, and any ambiguity be resolved in favor of lenity. United States v. Bass, 404 U.S. 336, 92 S.Ct. 515.

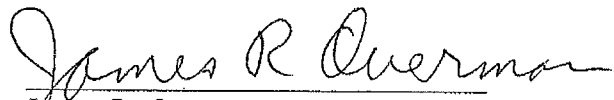
Businessmen must not be left to guess the meaning of regulations. Winters v. New York, 333 U.S. 507.

In criminal prosecution, unclarity alone is enough to resolve the doubt in favor of the defendant. United States v. Mersky, 361 U.S. 431, 80 S.Ct. 459.

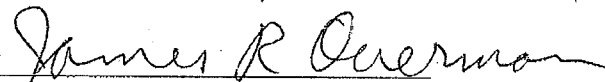
Vice of vagueness in criminal statutes is treachery. United States v. Cardiff, 344 U.S. 174, 73 S.Ct. 189.

The Respondent in this alleged complaint did not receive any prior notice that his conduct was even close to illegal or improper.

Sincerely,


James R. Overman

Precision Herbs L.L.C.,

By 
James R. Overman, President